AUG 12 2008

510(k) Summary

K081647

510(k) Owner: Xodus Medical, Inc.
Westmoreland Business & Research Park
702 Prominence Drive
New Kensington, PA 15068
Phone: 724-337-5500
Fax: 724-337-0555
Contact: Brenda Niel (Quality Assurance Manager)

Establishment Registration Number: 2530138

Date Prepared: 6/10/08

Device Information

Trade/Device Name: Electrosurgical Pencil with PTFE Coated & Uncoated Electrode Tips
Common Name: ES Pencil
Classification Name: Electrosurgical, Cutting & Coagulation Device & Accessories
Regulation Number: 21 CFR 878.4400
Product Code: GEI
Regulatory Class: II

Predicate Device

Device Name: Electrosurgical Pencil with PTFE Coated & Uncoated Electrode Tips
Common Name: ES Pencil
510 (k) Number: K965054
510 (k) Owner: MegaDyne Medical Products, Inc.
Classification Name: Electrosurgical, Cutting & Coagulation Device & Accessories
Regulation Number: 21 CFR 878.4400
Product Code: GEI
Regulatory Class: II

510(k) Summary

Device Description

This device is used to activate the CUT and COAGULATE modes of an electrosurgical generator in order to cut soft tissue via a handheld push button or rocker switch controlled electrosurgical pencil. The body of the device has a molded plastic housing with either two buttons (one for cut and one for coagulate) or a rocker switch located at the distal end of the pencil. A ten foot cable exiting the housing features a universal three prong plug allowing the pencil to be connected to the monopolar side of a standard electrosurgical generator. A PTFE coated electrode or an uncoated stainless steel electrode will be packaged with this device with the option of including an insulated holster.

The Holster serves as an insulated container to store the pencil while it is inactive in order to avoid accidental activation when not in use. The holster conveniently attaches to a surgical drape.

The uncoated stainless steel electrode is used to cut and coagulate soft tissue. The PTFE coated electrode is a stainless steel electrode coated with a non-stick material (PTFE), which is also used to cut and coagulate soft tissue. The PTFE coating reduces the build up of eschar on the electrode during use; thus, eliminates the need to clean or "scrape" the electrode on an abrasive surface to remove the eschar buildup.

This device is a single use, disposable device which will be sold sterile and bulk non-sterile to be sterilized by the customer. Electrode tips are also single use, disposable devices which may be sold individually sterile or bulk non-sterile to be sterilized by the customer.

Intended Use

The intended use for this device is to conduct monopolar electrosurgical energy from an electrosurgical unit (ESU), to an electrosurgical electrode consequently to the intended tissue to be cut and/or coagulated.

Indications: General, urologic, thoracic, plastic/reconstructive, gynecologic, laparoscopic and arthroscopic surgical procedures.

Technological Characteristics Comparison

The Xodus Medical disposable Electrosurgical Pencil is substantially equivalent in material and operation to other electrosurgical pencils already on the market. All materials used to manufacture the Electrosurgical Pencils and Electrodes are non-toxic and are currently being utilized by our competitor's in previously marketed devices. There are no new technological characteristics associated with this device; thus, no new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Xodus Medical, Inc.
% Ms. Brenda Niel
Quality Assurance Manager
Westmoreland Business & Research Park
702 Prominence Drive
New Kensington, Pennsylvania 15068

AUG 12 2008

Re: K081647
Trade/Device Name: Electrosurgical Pencil with PTFE Coated & Uncoated Electrode Tips
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: June 10, 2008
Received: June 12, 2008

Dear Ms. Neil:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081647

Device Name: Electrosurgical Pencil with PTFE Coated & Uncoated Electrode Tips

Indications for Use:

The intended use for this device is to conduct monopolar electrosurgical energy from an electrosurgical unit (ESU), to an electrosurgical electrode consequently to the intended tissue to be cut and/or coagulated.

Prescription Use X (Per 21 CFR 801 Subpart D) OR Over-The Counter Use____ (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081647